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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/827,686	04/06/2001	John Rizzotto	PAR-100US	5077
75	90 06/12/2003	,		
James C. Simmons Ratner & Prestia			EXAMINER	
One Westlakes, Berwyn, Suite 301 P.O. Box 980			WALLS, DIONNE A	
Valley Forge, PA 19482-0980		ART UNIT	PAPER NUMBER	
			1731	8
			DATE MAILED: 06/12/2003	_

Please find below and/or attached an Office communication concerning this application or proceeding.

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•		Application No.	Applicant(s)
	Office Action Commons	09/827,686	RIZZOTTO ET AL.
	Office Action Summary	Examiner	Art Unit
		Dionne A. Walls	1731
Period fo	The MAILING DATE of this comn or Reply	nunication appears on the cover s	heet with the correspondence address
THE I Externation If the If NO Failu Any	ORTENED STATUTORY PERIOD MAILING DATE OF THIS COMMINION of time may be available under the provisions of time may be available under the provision of time may be available under the provision period for reply specified above is less than this period for reply is specified above, the maximure to reply within the set or extended period for eply received by the Office later than three more adparent term adjustment. See 37 CFR 1.704(to the content of the c	UNICATION. sions of 37 CFR 1.136(a). In no event, however communication. rty (30) days, a reply within the statutory minim m statutory period will apply and will expire SI reply will, by statute, cause the application to b ths after the mailing date of this communicatio	er, may a reply be timely filed um of thirty (30) days will be considered timely. X (6) MONTHS from the mailing date of this communication ecome ABANDONED (35 U.S.C. § 133).
1)[Responsive to communication(s	s) filed on <i>08 April 2003</i> .	\
2a)⊠	This action is FINAL .	2b) This action is non-fina	al.
3)	Since this application is in condi	<i>,</i> —	nal matters, prosecution as to the merits
Dianasiti	closed in accordance with the p	ractice under <i>Ex parte Quayle</i> , 1	
· _	on of Claims		
	Claim(s) <u>1,4-9,18 and 22-26</u> is/a		
	4a) Of the above claim(s) i	s/are withdrawn from considerat	ion.
· <u> </u>	Claim(s) is/are allowed.	en unionto d	
	Claim(s) <u>1,4-9,18 and 22-26</u> is/ar	-	
	Claim(s) is/are objected to		4
	Claim(s) are subject to res on Papers	striction and/or election requirem	ent.
9)[The specification is objected to by	the Examiner.	
10) 🔲 -	Γhe drawing(s) filed on is/a	re: a)□ accepted or b)□ objected	to by the Examiner.
		objection to the drawing(s) be held	-
11) 🔲 -			b) disapproved by the Examiner.
		e required in reply to this Office action	n.
	The oath or declaration is objected	to by the Examiner.	
Priority u	nder 35 U.S.C. §§ 119 and 120		
13)	Acknowledgment is made of a cla	aim for foreign priority under 35 l	J.S.C. § 119(a)-(d) or (f).
a)[☐ All b)☐ Some * c)☐ None o	of:	
	<u> </u>	rity documents have been receive	
	_	rity documents have been receive	
		ernational Bureau (PCT Rule 17.	
			U.S.C. § 119(e) (to a provisional application
	☐ The translation of the foreign		
	cknowledgment is made of a claim	m for domestic priority under 35	U.S.C. §§ 120 and/or 121.
Attachment	` '	_	
2) 🔲 Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Reviev nation Disclosure Statement(s) (PTO-1449	w (PTO-948) 5) ☐ N	terview Summary (PTO-413) Paper No(s) otice of Informal Patent Application (PTO-152) ther:
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DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1, 4-8, 18, 24-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Finberg (US. Pat. No. 3,067,068).

Finberg discloses a chewing composition/tobacco substitute comprising cabbage leaves as a carrier, in combination with papaya leaves, both of which are heated such that, in the final product, the water content is between about 5 and about 14 percent by weight (corresponding to the claimed "moisture content at or below 8% by weight"). The chewing composition may include humectants, such as glycerin; flavoring agents, such as apple cider (corresponding to the claimed "water soluble but not water containing flavoring ingredient...liquid form"); and other sweetening agents, such as vanillin.

Finberg teaches that the chewing composition can be produced in any conventional form, including shredded/strand form. (col. 5, line 52-col. 6, line 34; col. 7, line 68, col.

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10, line 17-col. 12, line 17; see examples 1-4). While Finberg may not specifically state that the plant material has at least 30% intact cell walls, it is presumed that the cabbage leaves of its invention inherently possesses this characteristic since there is no requirement that, during the processing of the chewing product, the leaf composition be handled in a manner which would break the cellular structure of the vegetable material. In the alternative, the cell walls of Finberg would obviously be at least 30% intact due to the fact that that leaves comprising the chewing composition are merely mixed together, heated under pressure, and molded into a desired shape for subsequent shredding or the like. Further, it follows that the flavoring ingredients would be such that they would be capable of entering said cell walls since this must occur in order to appreciate the benefits of the ingredients in the final product. Lastly, since the preamble contains "comprising" language, the claims are open to include substances in addition to the edible cabbage carrier, flavoring ingredient and humectant combination. Therefore, even though the Finberg reference teaches a product with a combination of cabbage and papaya leaves, the disclosure still reads on the claims because the preamble does not recite "a chewable flavor delivery system consisting of in combination:....", even though the claim recitation now requires a carrier "consisting of an edible...plant material being 100% cabbage leaves".

4. Claims 1, 4-6, 8, 18, 23 and 25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Aebi et al (US. Pat. No. 5,368,873).

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Aebi discloses a vegetable composition which can comprise 100% cabbage leaves as a carrier, infused with humectant that can also include other sweeteners, such as a combination of fructose, and other sugars (corresponding to the claimed "water soluble...flavoring ingredient/sweetening agent") . In the final product, the water content is preferably from 2-6% by weight of water (corresponding to the claimed "moisture content at or below 8% by weight"). Aebi teaches that it is important to have the vegetable pieces, used in the product, of a size which facilitates infusion of the humectant, and that such size is preferably 1/16 - 3/16 inch in thickness. Example 8 discloses that the cabbage is sliced (corresponding to the claimed "strand"), and Example 10 discloses that the cabbage is ground such that it passes through a 20 mesh screen (corresponding to the claimed "pass a 16/20 mesh and be retained on a 30 mesh screen") (see entire reference). While Aebi may not specifically state that the plant material has at least 30% intact cell walls, it is presumed that the cabbage leaves of its invention inherently possesses this characteristic since it is clear that the disclosure teaches against damaging the leaf structure (see col. 9, line 67). In the alternative, the cell walls of Finberg would obviously be at least 30% intact due to the fact that that leaves comprising the vegetable composition are handled in such a way so as to minimize structural damage. Further, it follows that the flavoring ingredients are capable of entering the intact cell walls since this obviously must occur in order to appreciate the benefits of said ingredients in the final product.

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Claim Rejections - 35 USC § 103

5. Claims 4-6, and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finberg (US. Pat. No. 3,067,068) in view of Garber (US. Pat. No. 2,331,830).

While Finberg may not specifically state that the cellulosic plant material of its invention is in a granular form, it does state that the chewing composition can be in any form that such compositions are conventionally provided (col. 5, lines 52-53). Further, Garber discloses chewing tobacco compositions that can be provided as granular particles (page 2, col. 2, lines 32-33). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the chewing composition of Finberg in the form of granules since this form of chewing tobacco is known in the art as evidenced by the Garber disclosure. While there may be no specific articulation of the claimed mesh sizes for the chewing composition of Finberg modified by Garber, it would have been obvious to one having ordinary skill in the art at the time of the invention to optimize the granule size and arrive at the claimed mesh sizes, after routine experimentation, in order to produce a chewing composition with granules having ideal surface area to effectively hold the conditioning agents. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA)

6. Claims 9 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi (US. Pat. No. 5,368,873) in view of Nonomura et al (US. Pat. No. 5,597,400).

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While the chewing composition of Aebi et al may not specifically state that the cabbage of its vegetable product is green cabbage, this limitation is not deemed to impart any patentable distinction to the claims because green cabbage classified as Brassica oleracea capitata is a commercially known plant/vegetable material, as evidenced by the Nonomura et al reference (col. 11, lines 8-9). Therefore, one having ordinary skill in the art would have been motivated to use it as the cabbage leaf vegetable material in the chewing composition of Aebi et al because of its market availability. Further, while Aebi modified by Nonomura et al may not disclose that the cabbage of its chewing composition is "freeze dried", since the claims are drawn to a product, patentability of the green cabbage claimed is based on differences in product characteristics, i.e. moisture content, not on its method of production. Absent evidence to the contrary, the Examiner presumes that the cabbage of Aebi et al modified by Nonomura et al is "characteristically" the same as the freeze-dried cabbage which is claimed.

7. Claims 1 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rozacky et al (US. Pat. No. 3,702,615).

Rozacky et al discloses a non-tobacco, chewing product which can comprise 100% shredded cabbage carrier, humectant, fruit/plant extract (corresponding to the claimed "sweetening agent"), and flavors (see entire reference). While Rozacky may not specifically disclose that the cabbage has a moisture content of at or below 8% by weight, it does state that the product can be dried to a suitable moisture content (see claim 1). Further, it would have been obvious to one having ordinary skill in the art at

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the time of the invention to optimize the moisture content of the final product and arrive at the claims parameters, after routine experimentation, in order to produce an optimal non-tobacco composition. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA)

While Rozacky et al may not specifically state that the cabbage material has at least 30% intact cell walls, it is presumed that the cabbage leaves of its invention inherently possesses this characteristic since there is no requirement that, during the processing of the chewing product, the leaf composition be handled in a manner which would break the cellular structure of the vegetable material. In the alternative, the cell walls of Finberg would obviously be at least 30% intact due to the fact that that leaves comprising the chewing composition are merely mixed together, heated under pressure, and molded into a desired shape for subsequent shredding or the like. Further, it follows that the flavoring ingredients would be such that they would be capable of entering said cell walls since this must occur in order to appreciate the benefits of the ingredients in the final product.

Lastly, while Rozacky may not disclose that the humectant utilized in the product is glycerin or propylene glycol, or that the flavorant used is water soluble, but not water-containing, (such as sucrose, fructose, etc) use of either of these types of flavorants/humectants would have been obvious to one having ordinary skill in the art since they are conventional choices for flavorants and humectants in the tobacco art.

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8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rozacky et al (US. Pat. No. 3,702,615) in view of Nonomura et al (US. Pat. No. 5,597,400).

While the chewing composition of Rozacky et al may not specifically state that the cabbage of its vegetable product is green cabbage, this limitation is not deemed to impart any patentable distinction to the claims because green cabbage classified as Brassica oleracea capitata is a commercially known plant/vegetable material, as evidenced by the Nonomura et al reference (col. 11, lines 8-9). Therefore, one having ordinary skill in the art would have been motivated to use it as the cabbage leaf vegetable material in the chewing composition of Rozacky et al because of its market availability. Further, while Rozacky et al modified by Nonomura et al may not disclose that the cabbage of its chewing composition is "freeze dried", since the claims are drawn to a product, patentability of the green cabbage claimed is based on differences in product characteristics, i.e. moisture content, not on its method of production. Absent evidence to the contrary, the Examiner presumes that the cabbage of Rozacky et al modified by Nonomura et al is "characteristically" the same as the freeze-dried cabbage which is claimed.

Response to Arguments

- 9. Applicant's arguments filed April 8th, 2003 have been fully considered but they are not persuasive.
 - With respect to Applicant arguments regarding the Finberg reference, and that its disclosure teaches a composition that must include papaya leaves, in addition to cabbage, the Examiner believes that her position

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on this issue has been adequately addressed in the above rejection. Briefly stated here, the Examiner <u>does not disagree</u> that the Finberg reference requires both papaya leaves and cabbage leaves in its final product; *however*, the Examiner contends that the claims, as presently stated, are open to the inclusion of material, <u>in addition to</u> the 100% cabbage carrier, humectant and flavoring combination because of the "<u>comprising</u>" language in the preamble. Therefore, the Finberg reference can be properly applied to the claims.

- Applicant argues that the Finberg reference teaches flavoring of cabbage leaves prior to grinding, which contrasts with Applicant's invention which teaches grinding before flavoring; however, Applicant has not claimed any particular order of flavoring/grinding. These claims are drawn to a product, not a method. Therefore, any method step differences, i.e. grinding then flavoring, would not patentably distinguish the claims from the reference since this limitation does not "characteristically" or "structurally" distinguish the claims from the reference.
- Applicant argues that Finberg does not teach drying the initial product to a moisture content of 8%, but is concerned that the final moisture content may rise to at least 14% by weight. However, the Examiner disagrees. Clearly, stated in col. 11, lines 33-43, Finberg discloses that the last heating step, in the production of the product, is designed to provide a product having a moisture content of anywhere between 5-

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14%. This range would include the 8% moisture content which is claimed.

Applicant argues that Finberg does not teach the form in which the papaya leaves must be used; however, the Examiner points out that the Finberg reference indicates that the final product (which would include both papaya leaves and cabbage leaves) can be in any conventional form. And, the Garber reference is introduced merely to teach that typical forms for chewing product, in the tobacco area, are either strands, shreds or granules.

Any remaining arguments that are not addressed here, the Examiner believes, has been adequately addressed in the above rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne A. Walls whose telephone number is (703) 305-0933. The examiner can normally be reached on Mon-Fri, 7AM - 4:30PM (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven P. Griffin can be reached on (703) 308-1164. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

Dionne A. Walls

June 11, 2003